

71QSCI16330008

Nidek YC-1800 YAG Laser (36730561300046) One each Nidek Co YC-1800 YAG laser system, photocoagulation apparatus, surgical. An electronic item designed to produce a narrow intense beam of light, using a light energy, such as carbon dioxide, argon, infrared, neodymium, etc., and laser beam, for Required local heating up of the tissue to cause a coagulation action. Light energy can be adjusted to produce such tissue changes as Dehydration (cell contraction), protein coagulation, tissue Vaporization causing a cutting effect, and the like. Such applications Are used in surgery. System consists of desk, monitor, computer (no hard drive), and cabling. Items may need unknown repairs. Purchaser is responsible for packing, shipping, handling, loading, etc. Please call to schedule viewing/pickup date and time. POC Melvin Cullum 918-577-3709, Thelma Nash 918-577-3024, or Jacob Chavez 918-577-3161; E-mail VHAMUSNX@VA.GOV.

** Winning bidder required to complete and submit the attached "71QSCI16330008Medical Devices SOI.pdf" prior to removal. E-mail to mark.maxwell@gsa.gov with a Cc to vhamusnx@va.gov is the preferred method of submission**

MEDICAL DEVICES. Purchasers of all medical equipment listed in the Invitation for Bid (IFB) shall certify and assure in writing that such item will b e used or resold only under the conditions specified below:

Medical device items are subject to the laws and regulations administered by the Food and Drug Administration (FDA). Provisions of the governing statute, the Federal Food, Drug and Cosmetic Act appear in 21 U.S.C. 331, ET. Seq. In summary, the Act prohibits the movement in interstate commerce of medical devices that are misbranded or adulterated. The Act authorizes FDA to initiate criminal enforcement proceedings against companies and/or individuals responsible for violations of its provisions. Moreover, the Act authorizes FDA to initiate civil proceedings to seize, or enjoin the distribution of such items.

It shall, also, be the responsibility of all purchasers to comply with local, state, or other applicable laws.

The following certificate, to be a separate attachment to the Invitation for Bid, is required by FDA to purchase the medical device items identified in the Invitation.

I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device item identified in the IFB. I, also, certify that prior to sale or use of such a device, I will take assurance that such a device is not adulterated or misbranded within the meaning of those terms in the Federal Food Drug and Cosmetic Act (21 U.S.C., et Seq.).

Signature

Date

Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C. 331, et. Seq.), I certify that I either will sell or otherwise proffer the medical device item identified in the IFB to persons described in the above, or will not use this item(s) for their original or usual intended use, for any other medical use.

Signature

Date

False or misleading statements may result in a fine of not more than \$10,000 or imprisonment for not more than five (5) years, or both (18 U.S.C. 1001).